



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 876, 878, and 886

[Docket No. FDA-2018-N-3066

Medical Devices; Classification of Accessories Distinct from Other Devices; Proposed List of Accessories Suitable for Class I; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; request for comments.

SUMMARY: As required by the FDA Reauthorization Act of 2017 (FDARA), the Food and Drug Administration (FDA or Agency) has identified a list of accessories for which the Agency believes general controls alone are sufficient to provide reasonable assurance of safety and effectiveness, so the accessories could be in class I. FDA is publishing this document proposing to classify these accessories into class I and distinct from other devices, as well as seek public comment in accordance with procedures established by FDARA. This document does not represent FDA's final determination with respect to the proposed accessories listed in this document.

DATES: Submit either electronic or written comments on the document by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]

The <https://www.regulations.gov> electronic filing system will accept comments until midnight

Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2018-N-3066 for "Medical Devices; Classification of Accessories Distinct from Other Devices; Proposed List of Accessories Suitable for Class I; Request for Comments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the

body of your comments and you must identify this information as "confidential."

Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ian Ostermiller, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5454, Silver Spring, MD 20993-0002, 301-796-5678.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On August 18, 2017, FDARA was signed into law (Pub. L. 115-52). Section 707 of FDARA amended section 513(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and, among other amendments, created a process for FDA to propose a list of accessories suitable for distinct classification into class I (see section 513(f)(6)(D)(i) of the FD&C Act (21 U.S.C. 360c(f)(6)(D)(i))). Section 707 of FDARA mandated that FDA make the first such proposal within a year of enactment of FDARA, and FDA is publishing this document in accordance with this statutory mandate.

Section 201(h) of the FD&C Act defines "device" to include, among other articles, an "accessory" (see 21 U.S.C. 321(h)). As such, all articles that meet the definition of "device", including accessories, are regulated under the FD&C Act. Based on sections 201(h) and 513(f)(6) of the FD&C Act, we have described our current thinking on which devices we would generally consider to be accessories in the guidance document, "Medical Device Accessories--Describing Accessories and Classification Pathways," available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429672> ("Accessories Guidance"). That guidance defines an accessory as a "finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices."

Section 513 of the FD&C Act defines three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (premarket approval). Some accessories may be granted marketing authorization as part of a submission for another device with which they are intended to be used and in class II or III that, if considered distinctly from another device (such as the parent device), may be suitable for classification into class I if general controls alone are sufficient to provide a reasonable assurance of safety and effectiveness of the accessory.

Section 513(h)(1) defines general controls as the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 of the FD&C Act. These controls include, but are not limited to, provisions related to adulteration and misbranding, registration and listing, records and reports on devices, and good manufacturing practices. The regulations for good manufacturing practices are under 21 CFR part 820, the Quality System regulation. Subject to

the exceptions identified in § 820.30(a)(2) (21 CFR 820.30(a)(2)) for specific devices and those automated with computer software, design controls under § 820.30 do not generally apply to a class I device.

This document represents FDA's compliance with FDARA's requirement to identify the first list of accessories suitable for distinct classification into class I. As required by FDARA, we are providing you with the opportunity to provide comment. Once the comment period ends, we will consider the comments and publish in the *Federal Register* a final action classifying such suitable accessories into class I.

## II. Factors for Consideration

The classification of each accessory will be based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used (see section 513(f)(6)(A) of the FD&C Act).

In general, we considered an accessory to be eligible for classification into class I distinct from another device if the accessory: (1) is not for use in supporting or sustaining human life, or of substantial importance in preventing impairment to human health; (2) does not represent a potential unreasonable risk of illness or injury; and (3) general controls alone would be sufficient to provide a reasonable assurance of safety and effectiveness of the accessory.

Note that by regulation, design controls apply to class I devices only if the devices are automated with computer software or are listed under § 820.30(a)(2)(ii). Thus, if an accessory is not automated with computer software but would require design controls to provide reasonable assurance of safety and effectiveness, we did not consider it eligible for classification through the final action based on this document.

You may wish to propose additional accessories as suitable for distinct classification into class I using the factors described above where the accessories are otherwise eligible for classification under section 513(f)(6)(D)(i) of the FD&C Act. Should you wish to propose additional accessories, your comment should briefly explain why you think general controls alone will provide reasonable assurance of safety and effectiveness. Conversely, should you disagree with any of the proposed accessories for class I, your comments should briefly explain why additional regulatory controls, such as premarket review through a 510(k) submission or premarket approval (PMA), are necessary to provide reasonable assurance of safety and effectiveness.

### III. Policy Clarification for Classification of Certain Accessories Used in Orthopedic Surgery

Certain manual orthopedic instruments that are for use with other devices in orthopedic surgery meet FDA's definition of an accessory described in the Accessories Guidance. Accordingly, we are clarifying our intended regulatory approach for certain accessories used in orthopedic surgery to distinguish which accessories may be candidates for classification per section 513(f)(6)(D)(i) of the FD&C Act.

Instruments for use in orthopedic surgery vary widely from general manual surgical instruments used to manipulate tissue to more complex accessories specifically designed for use with a parent device/system. Orthopedic manual surgical instruments are classified in § 888.4540 (21 CFR 888.4540), and many "general use" instruments fall within this classification. This regulation pertains to "nonpowered hand-held device[s] intended for medical purposes to manipulate tissue, or for use with other devices in orthopedic surgery." These devices are class I, subject to general controls, and exempt from premarket notification procedures, subject to the limitations of exemptions in 21 CFR 888.9. This classification was based upon

recommendations provided to FDA by the Orthopedic Device Classification Panel (the Panel) in October 1977 regarding classification of medical devices in commercial distribution before May 28, 1976. The Panel identified the following risks to health for this device type: "Tissue damage and adverse tissue reaction: Inadequate mechanical properties, such as lack of material strength of the device, may result in device fracture and possible tissue damage and, if fragments of the fractured device remain in the tissue, an adverse tissue reaction may result" (47 FR 29052).

FDA agreed that class I was appropriate because general controls alone were sufficient to mitigate the risk of tissue damage and adverse tissue reaction associated with inadequate mechanical properties and provide a reasonable assurance of the safety and effectiveness of these devices. Over time, manufacturers have developed and sought to market orthopedic instrumentation with designs unique to a device system, and these types of instruments may present new or different risks compared to inadequate mechanical properties. For example, certain device-specific instruments are accessories and require precise technical specifications or design characteristics to function as intended to support, supplement or augment the parent device, and if not designed appropriately, could cause implant malpositioning or migration. Accordingly, FDA considers design controls (see § 820.30) to be an important element in the regulation of device-specific accessories, among other regulatory controls, to ensure appropriate compatibility between the accessory and the parent device. In contrast, class I orthopedic manual surgical instruments do not require such controls.

Instruments that are "device-specific," or designed for use with a specific parent device/system and thus are accessories, have historically been reviewed in the same premarket submission as the parent device. In an effort to ensure a common understanding as to which orthopedic accessories fall under the existing class I regulation (§ 888.4540), and which devices



do not and, therefore, may be candidates for classification under section 513(f)(6)(D)(i) of the FD&C Act, we propose the following definition: A device-specific orthopedic instrument is considered to be an accessory designed specifically for appropriate implantation or placement of the parent device, based upon unique dimensions, geometry, and/or deployment. In these cases, design specifications are critical to the proper use of the accessory in supporting, supplementing, and/or augmenting the performance of the parent device and/or a specific system. This excludes general use orthopedic instruments that are provided as a part of a system.

It is often necessary for orthopedic instruments to be described in a premarket submission (e.g., 510(k), PMA) to evaluate that the parent device functions as intended. Such orthopedic instruments may be appropriately classified in an existing class I regulation (§ 888.4540) if they do not meet the definition of a device-specific orthopedic accessory above and their risk profile and necessary regulatory controls are commensurate with that of orthopedic manual surgical instruments. If they do meet the definition of a device-specific orthopedic accessory above, then such orthopedic accessories may still be eligible for classification under section 513(f)(6)(D)(ii) of the FD&C Act.

We welcome comments to help identify accessories in other product areas where the classification of the accessory relative to the parent device may be unclear and would benefit from this type of policy clarification.

#### IV. Proposed List of Accessories that May Be Suitable for Distinct Classification into Class I

We are proposing the following accessories, which have been granted marketing authorization as part of a premarket submission (i.e., 510(k), De Novo classification request, or PMA) for another device with which they are intended to be used, as suitable for distinct classification into class I (see table 1). When we publish the final list of accessories based on

this list and the factors in section II, we will consider those accessories classified into class I, distinct from other devices, through such action.

We would place each of these accessories in 21 CFR part 876, 878, or 886, as appropriate. Each of these accessories would be class I, exempt from the premarket notification procedures in 21 CFR part 807, subject to the applicable limitations of exemption (i.e., 21 CFR 876.9, 878.9, or 886.9). We intend to make conforming changes to existing classification regulations as appropriate.

Table 1.--Proposed Accessories for Classification into Class I and Distinct from Other Devices

Current Status of Accessory		
Current Classification Regulation (21 CFR)	Device Type (Existing Product Code)	Proposed Device Type Identification
876.1075	Gastroenterology-urology accessories to a biopsy instrument (FCG)	Accessories used to remove a specimen of tissue for microscopic examination by cutting or aspiration. This generic type of device includes a syringe for specimen aspiration and a biopsy channel adaptor. This device does not include accessories to biopsy instruments used in other medical specialty areas.
876.3350 and 876.3630	Penile implant surgical accessories (JCW and FHW)	Manual devices designed to be used for surgical procedures associated with the implantation of a penile inflatable implant or penile rigidity implant. This generic type of device includes the cylinder sizer, cylinder insertion tool, connector assembly tool, incision closing tool, corporeal dilator, tubing passer, measurement tool or tape, temporary tubing plug, and hemostat shod tubing.
876.4620	Ureteral stent accessories (FAD)	Accessories that aid in the insertion of the ureteral stent that is placed into the ureter to provide ureteral rigidity and allow the passage of urine. This generic type of device includes the stent positioner, wire guide, and pigtail straightener.
876.5010	Biliary stent, drain, and dilator accessories (FGE)	Manual devices that aid in the introduction and connection of biliary stents, drains, or dilators. This generic type of device includes the guiding catheter, pushing catheter, pigtail straightener, flap protector, nasal transfer tube, and drainage connecting tube.
876.5090	Suprapubic catheter accessories (KOB)	Manual devices that are used to facilitate the placement of a suprapubic catheter. This generic type of device includes the introducer, access dilator, and peel-away sheath.
876.5280	Implanted mechanical/hydraulic urinary continence device surgical accessories (EZY)	Manual devices designed to be used for surgical procedures associated with the implantation of an implanted mechanical/hydraulic urinary continence device. This generic type of device includes the measurement tool or tape, connector assembly tool, temporary tubing plug, incision closing tool, tubing passer, and hemostat shod tubing.

Current Status of Accessory		
Current Classification Regulation (21 CFR)	Device Type (Existing Product Code)	Proposed Device Type Identification
878.5070	Air-handling apparatus accessory (FYD)	Supplementary device that is intended to be used with an air-handling apparatus for a surgical operating room. This device provides an interface between the components of the device or can be used to switch electrical power. This generic type of device includes fittings, adapters, couplers, remote switches, and footswitches.
No corresponding CFR Section	Corneal inlay inserter handle (LQE)	Hand-held device intended to be used as an accessory to a corneal inlay inserter. The device extends the length of the inlay inserter to aid in delivering the inlay implant.

## V. Paperwork Reduction Act of 1995

This document refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
807, subpart E	Premarket notification	0910-0120
814, subparts A through E	Premarket approval	0910-0231
"De Novo Classification Process (Evaluation of Automatic Class III Designation)"	De Novo classification process	0910-0844
800, 801, and 809	Medical Device Labeling Regulations	0910-0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910-0073
"Medical Device Accessories--Describing Accessories and Classification Pathways for New Accessory Types."	Medical Device Accessories	0910-0823

Dated: August 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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